DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5300

IN REPLY REFER TO
6530/25.2
Ser M3F2/0085
01 Aug 03

From: Chief, Bureau of Medicine and Surgery

Subj: IMPLEMENTATION OF WEST NILE VIRUS (WNV) NUCLEIC ACID TESTING (NAT); SINGLE DONOR TESTING UNDER INVESTIGATIONAL NEW DRUG (IND) PROTOCOL

Ref: (a) BUMED ltr 6530/2.5 Ser M3F2/0085 of 4 Jun 03

Encl: (1) Acknowledgement of Receipt and Implementation

1. The Navy Blood Program Office (NBPO) provides procedural guidance and operational policies for Navy and Marine Corps facilities responsible for collection, storage, and/or transfusion of blood products. Reference (a) revised the guidelines for WNV screening, deferral, testing, and lookback. The NBPO is providing implementation guidance to all Navy blood collection and testing facilities on the Clinical Investigational Protocol for the Transcription Mediated Amplification (TMA) WNV assay for individual donor testing. The implementation date for WNV NAT of all blood collected by Navy blood donor centers is 8 August 2003.

2. Single Donor WNV NAT will be performed on blood specimens from all allogeneic, autologous, and apheresis blood donations collected under the Navy's Food and Drug Administration Blood Establishment License 635. The Army has contracted with and will be operating under GEN-PROBE's IND protocol. All Department of Defense (DoD) blood donor collection facilities will follow the standardized research protocol and use the informed consent documents that have been approved by the DoD Human Subject Research Review Board (HSRRB), which will be the Institutional Review Board (IRB) of record for this protocol. LTC Elaine Perry, Director, Robertson Blood Center, Fort Hood, Texas, has been identified as the Principal Investigator (PI) for the protocol.

a. Each Navy blood collection site has a designated Sub-Investigator. It is the responsibility of the Sub-Investigator to ensure that the approved research protocol is strictly followed as written. Sub-Investigators must provide a courtesy copy of the entire research protocol to their local IRB for informational purposes only.

b. Any changes to the study protocol or in Sub-Investigators must be submitted to the PI. The PI will file the changes with the HSRRB for approval. Newly identified personnel will be required to submit a Curriculum Vitae and Good Clinical Practices (GCP) training certificates.

3. All Navy blood donor collection facilities must be thoroughly familiar with and strictly adhere to the IND/IRB protocol. Army testing sites that will perform WNV NAT under the IND include Robertson Blood Center (RBC), Ft Hood, Texas, Camp Memorial Blood Center (CMBC), Ft Knox, Kentucky, and Tripler Army Medical Center (TAMC), Tripler, Hawaii. All records pertaining to this study must be kept for a minimum of two years after FDA licensure of WNV NAT single donor testing.

4. Before testing can begin:

a. The Blood Bank Medical Director, OIC, Civilian Supervisor and Quality Assurance Supervisor must read and understand the IND/IRB protocol that was sent from Army.

b. A person knowledgeable on the NAT process must be available on site or by phone during all blood collection procedures to answer any donor questions related to this study or the informed consent process.

c. Staff designated to present the informed consent must be trained and thoroughly understand all the aspects the initial consent form. All training must be documented.

d. Site-specific consent forms provided by the Army must be used.

5. Consent Form - There are two consent forms:

a. Initial Blood Donation - All donors must agree to participate in the study and sign the initial blood donation consent form prior to blood donation. Donors who do not want to participate in the study will NOT be allowed to donate blood. The collection site must maintain the donor consent forms and must be able to cross-reference them to the donor's completed DD Form 572.

b. Follow-up Evaluation - Those blood donors with reactive/positive results must sign a follow-up evaluation consent form for enrollment in the follow-up protocol. Each Navy blood collection site is encouraged to enroll donors who qualify for the follow-up study as soon as possible.

6. Blood Donors - All allogeneic and autologous blood donors must be given the initial blood donor consent form with the DD Form 572. The donor must be instructed to read the initial blood donation consent form and must be provided an opportunity to discuss it or ask questions. Only donors who agree to participate in the study by signing the initial blood donation consent form will be allowed to donate blood. Donors who do not want to participate in this study will NOT be allowed to donate. WNV NAT is being performed as a nation-wide study. All donors are required to participate in this study as a prerequisite to donating blood.

7. Donor Follow-up procedures - Donors who qualify must be called and encouraged to participate in the Follow-up Study and must be given the opportunity to read and sign the Follow-up Evaluation Consent Form. The Medical Director or OIC should oversee this process. Specimen collection and frequency for donor follow-up specimens must follow IRB/IND Protocols.

8. Implementation of WNV will require that an extra Plasma Preparation Tube (PPT) be collected on each donor. Donor demographics must be collected and sent using the Business Object report instruction that was provided to each Navy blood collection facility by Army.

9. Blood collected on and after 8 August 2003 must be WNV NAT tested and must be negative prior to the release of blood products. Products released prior to the completion of WNV NAT must be released using site-specific emergency release procedures for untested blood.

10. The DoD is participating with the American Red Cross and the American Blood Centers in submitting WNV positive testing data to the Center for Disease Control (CDC). The CDC will use this data to monitor and track the spread of WNV across the nation. The PI will send weekly reports to the Navy Blood Program Office. The Navy Blood Program Office will subsequently

forward Navy specific WNV testing data to the Armed Services Blood Program Office, which will provide it to the CDC.

11. Report cases of confirmed WNV infection to the Navy Environmental Health Center, Norfolk, Virginia (757) 953-0700. All Navy facilities must follow the donor and patient lookback policy for WNV when a donor tests positive for WNV or WNV related post donation information is received, or when a recipient with a recent diagnosis of WNV who received a blood transfusion or organ donation is identified per reference (a).

12. A Biological Product Deviation report will be required if post-donation information related to WNV is received in cases where product retrieval and quarantine and/or notification of recipients of prior or subsequent collections from the donor occurs. If a suspect donation results in fatality in a transfusion recipient, a report of the fatality must be submitted to the FDA.

13. Each BDC must incorporate the Army standardized research protocol and informed consent documents procedure into current practices and train staff to insure the policy is adequately implemented as soon as possible but not later than **08 Aug 03.** All Navy facilities are to return enclosure (1) to BUMED-M3F2 by **08 Aug 03** to indicate receipt of the policy and dissemination to management staff and appropriate healthcare providers.

14. Points of contact for this matter are Ms. Jan Sigmon, QA Manager, or myself at DSN 762-3434 or (202) 762-3434.

M. C. LIBBY
By direction

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ACKNOWLEDGMENT OF RECEIPT
AND
IMPLEMENTATION

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Identifier: BUMED ltr 6530/25.2 Ser M3F2/ 0085		**Date: 01 Aug 03**

The Navy Blood Program must monitor receipt and change control at each of the Surgeon General's facility identified under the Food and Drug Administration's License 635. The Navy Blood Program's policy for above subject matter was received and implemented as indicated below.

Note: SIGN AND RETAIN ORIGINAL FOR YOUR FILES. COPY AND FAX THIS FORM AS SOON AS POSSIBLE, BUT **NO LATER THAN 08 AUG 03** TO:

CHIEF, BUREAU OF MEDICINE AND SURGERY
NAVY BLOOD PROGRAM (M2F3)
2300 E STREET, NW
WASHINGTON, DC 20372-5300
FAX (202) 762-0930

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